

CHILDRENS ALLERGY RELIEF- diphenhydramine hcl tablet, chewable
Topco Associates, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TopCare 44-585

Active ingredient (in each chewable tablet)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - sneezing
 - itching of the nose or throat

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages
- marked drowsiness may occur

- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- find right dose on chart below
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Age (yr)	Dose (chewable tablets)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	1 to 2 chewable tablets (12.5 mg to 25 mg)
adults and children 12 years and over	2 to 4 chewable tablets (25 mg to 50 mg)

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

Questions or comments?

1-888-423-0139

Principal Display Panel

+TopCare

health®

NDC 36800-585-44

COMPARE TO CHILDREN'S BENADRYL® CHEWABLES ACTIVE INGREDIENT*

children's

Allergy Relief

DIPHENHYDRAMINE HCl 12.5 mg

CHEWABLE TABLETS - ANTIHISTAMINE

4-6

HOURS

DOSE

OUR PHARMACISTS

RECOMMEND

RELIEF OF:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

18 CHEWABLE

TABLETS

Chew or crush tablets completely before swallowing.

For Ages 6 to 11 Years

GRAPE

FLAVOR

actual size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Benadryl® Chewables.

50844 REV1218A58544

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

QUALITY

GUARANTEED

+TopCare
health®

**18 CHEWABLE
TABLETS**

children's Allergy Relief

DIPHENHYDRAMINE HCl 12.5 mg
ANTIHISTAMINE

NDC 36800-585-44

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COMPARE TO CHILDREN'S
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DIPHENHYDRAMINE HCl 12.5 mg
CHEWABLE TABLETS - ANTIHISTAMINE



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**18 CHEWABLE
TABLETS**

Chew or crush tablets completely
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For Ages 6 to 11 Years

**GRAPE
FLAVOR** actual size



TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT
IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

No Print / No Varnish
Lot no. & Exp. date



8

B-1910-585-44-BLR
REV1218A58544

for more information.
Call 1-888-423-0139
for more information.



**✓ QUALITY
GUARANTEED**

50844
REV1218A58544
of the registered trademark

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Children's Benadryl® Chewables.
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TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

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adults and children 12 years

2 to 4 chewable tablets

(12.5 mg to 25 mg)

children 6 to 11 years

1 to 2 chewable tablets

directed by a doctor

do not use unless

children 2 to 5 years

do not use

children under 2 years

Age (yr)

Dose (chewable tablets)

■ do not take more than 6 times in 24 hours

■ take every 4 to 6 hours, or as directed by a doctor

swallow tablets whole

■ chew or crush tablets completely before swallowing; do not

Directions ■ find right dose on chart below

Drug Facts (continued)

Warnings

Do not use

■ with any other product containing diphenhydramine, even one

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help or contact a Poison Control Center right away.

Antihistamine

Diphenhydramine HCl 12.5 mg

(in each chewable tablet)

Active ingredient

Purpose

COMPLETE PRODUCT INFORMATION

KEEP OUTER PACKAGE FOR

CHILDRENS ALLERGY RELIEF

diphenhydramine hcl tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-585
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

Product Characteristics

Color	purple	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	44;585
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-585-44	3 in 1 CARTON	03/20/2009	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part341	03/20/2009	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(36800-585)

Revised: 4/2021

Topco Associates, LLC